Office of Medical Cannabidiol, Iowa Department of Public Health

Laboratory Testing Requirements & Acceptance Criteria

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1.0 Introduction and Purpose

1.1 – Introduction

The vision of the Office of Medical Cannabidiol (OMC) at the Iowa Department of Public Health is to have a high-quality, effective, and compliant medical cannabidiol program for Iowa patients with serious medical conditions.

The OMC will work to balance a patient's need for access to low-cost treatments with the requirement to ensure the safety and efficacy of the products. Paramount to patient safety and care is making sure that each medical cannabidiol product sold to a patient is tested for harmful contaminants and that product labels accurately reflect the content and potency of the medical cannabidiol being dispensed.

1.2 – Purpose

The purpose of this document is to provide licensed Iowa medical cannabidiol manufacturers and laboratories with the required and recommended best practices for the testing and analysis of medical cannabidiol. The governing statute of the Office of Medical Cannabidiol is Iowa Code chapter 124E and the associated administrative rules are found in 641 Iowa Administrative Code chapter 154.

1.0 Introduction and Purpose

1.3 – Testing Protocol Overview

Testing of medical cannabidiol products in Iowa occurs at two stages of the manufacturing: *Process* lots and *packaged* lots. A process lot is the extracted and refined cannabis oil that is used to formulate final products. Process lots can be any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and is tested for pesticides, residual solvents, microbiological impurities, and heavy metals prior to being used to formulate products. Packaged lots are the final packaged products that are ready to be delivered to dispensaries, and are tested for their potency and consistency of cannabinoid content, as well as for microbiological impurities that may have been introduced during the packaging process.

Additionally, process lots and packaged lots can be in one of two stages of testing status: *standard* testing or *reduced* testing. For standard testing, sampling for both process and packaged lots is based on the production volume of that process or packaged lot. Standard testing is more robust, and designed to validate a manufacturer's methods for extraction, as well as their consistency of formulation and cleanliness of final product packaging. Once a manufacturer has successfully passed standard testing for process lots or packaged lots, they enter into reduced-testing status. A manufacturer may remain in reduced-testing status for two years for both process lots and packaged lots. A manufacturer shall return to standard testing for a given analyte if a failure is reported by a laboratory, or if it is determined by the Department that a process or packaged lot process has had a material change (Section 4.5 & 6.6). These testing protocols are described in more detail in the following sections.

** This document is subject to revision based on evolving best practices, updated scientific information or standards and guidelines, changes in laws or regulations, and other information relevant to the contents of the protocol. Criteria will not be effective until the Laboratory and Manufacturers have had the opportunity to comment, the Laboratory reviews the document, and it is hosted publicly on the Office of Medical Cannabidiol website.*

**Tests results that include a qualifying statement require department notice, review, and approval before the laboratory issues a certificate of analysis. "Qualify" is defined as a conditional statement to the test result that has the potential to impact the accuracy of the reported test result, i.e., the procedure was not followed as stated. Examples include, but are not limited to: quality control failures, lab accidents, and insufficient sample mass.*

2.0 Definitions

Acceptance criteria*:* The specified limits placed on characteristics of an item or method that are used to determine quality with the exception of microbiological testing. When acceptance criteria for microbiological quality are prescribed, the maximum acceptable counts are as follows:

Colony-Forming Unit (CFU)	Maximum Acceptable Count
10^1	20
10^2	200
10^3	2000

Reference: USP 1111 Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use.

Action level*:* The threshold value that provides the criterion for determining whether a sample passes or fails a test performed pursuant to 641 IAC 154.

Analyte: A chemical, compound, element, bacteria, yeast, fungus, or toxin to be identified or measured.

Batch: A specifically identified quantity of dried flower and other cannabis plant matter that is uniform in strain or cultivar, harvested at the same time, and cultivated using the same pesticides and other crop inputs.

Certificate of Analysis: A document released by the laboratory to the manufacturer and department that contains the concentrations of cannabinoid analytes and other measures approved by the department, and whether a sample passed or failed in accordance with 641 IAC 154.

Cannabinoid Content Testing: The testing of final medical cannabidiol products for cannabinoid analytes, including THC, THCa, CBD, CBDa (testing for the acid form is not required if a manufacturer uses a decarboxylation process prior to extraction).

Coefficient of variation (CV) = relative standard deviation (RSD) = 100 s/ $\bar{x}$

Department: The Iowa Department of Public Health.

2.0 Definitions

Formulation: A mixture of CBD, THC, and other cannabinoids in specific, determined concentrations or absolute amounts (i.e., mg per capsule). For example, a mixture of 10 mg/ml CBD and 10 mg/ml THC is one formulation, and a mixture of 5 mg/ml CBD and 5 mg/ml THC is a different formulation. Altering the amounts of THC and CBD may be considered a change in formulation.

Laboratory: The State Hygienic Laboratory at the University of Iowa or other independent medical cannabidiol testing facility accredited to Standard ISO/IEC 17025 by an ISO-approved accrediting body, with a controlled substance registration certificate from the Drug Enforcement Administration of the U.S. Department of Justice and a certificate of registration from the Iowa board of pharmacy, and approved by the department to examine, analyze, or test samples of medical cannabidiol or any substance used in the manufacture of medical cannabidiol.

Lot: A specific quantity of medical cannabidiol that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record. For the purposes of this document, there are process lots and packaged lots.

Lot Number: A unique numeric or alphanumeric identifier assigned to a lot by a manufacturer when medical cannabidiol is produced. The lot number shall contain a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of a lot of medical cannabidiol.

Measurement Uncertainty (MU): A non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurement, based on the information used. An initial estimate of MU is based on the validation data collected. Ongoing laboratory quality control will be used to update the MU estimate as necessary.

Medical Cannabidiol: Any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa* L. or *Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than 3 percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by rule.

2.0 Definitions

Process Lot: Any amount of cannabinoid concentrate or extract that is uniform, produced from one or more batches, and is tested for pesticides, residual solvents, and heavy metals prior to being formulated into products.

Package Lot: A finished lot of medical cannabidiol that has been packaged, but has not been transported or sold to a dispensary.

Qualify or Qualified Result: A conditional statement to the test result that has the potential to impact the accuracy of the reported test result, e.g., the procedure was not followed as stated.

Reduced Testing: The testing procedures for processes and formulations that have successfully completed Standard Testing procedures.

Relative Percent Difference or **RPD:** A comparative statistic used to calculate precision or random error. RPD is calculated using the following equation: RPD = absolute value ([primary sample measurement – duplicate sample measurement]) / ([primary sample measurement + duplicate sample measurement] / 2) × 100.

Relative Standard Deviation or **RSD:** The standard deviation expressed as a percentage of the sample mean. It is the coefficient of variation (CV) multiplied by 100. If any results are less than the limit of quantitation, then the absolute value of the limit of quantitation is used in the following equation: RSD = (s / x) × 100, where s = standard deviation and x = sample mean.

Stability Testing: After storage of an unopened package of medical cannabidiol, the contents shall not vary in concentrations of THC and CBD by more or less than 30 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids from the concentration indicated on the package label.

2.0 Definitions

Standard Deviation: The standard deviation, s, of n measurements is given by:

$$\sqrt{\sum_{i} \frac{(x_i - \overline{x})^2}{(n-1)}}$$

n= total number of values

x_i = each individual value used to calculate the mean

Standard Testing: Testing performed on process and packaged lots to determine whether a manufacturing process produces products that are homogenous, free of contamination, and true to a labeled or expected concentration within certain established parameters. Upon satisfactorily completing standard testing for a specific manufacturing process and cannabidiol formulation, a manufacturer enters reduced-testing status for that process and formulation.

3.0 Process Lot Sampling

3.1 – Process Lot Sampling Plan Overview

A manufacturer shall submit to the Department for approval a standard operating procedure (SOP) for sampling process lots. Samples submitted for process lot testing should be representative of the entire process lot. Development of sampling strategies is a requirement of licensed manufacturers described in 641 IAC 154.26(2). Manufacturers must contact the laboratory in advance of sampling. In addition, a manufacturer shall notify the Department two business days in advance of all sampling. The Department shall reserve the right to be present to verify a manufacturer's submitted sampling SOP for process or packaged lots.

One Container Method: Microbiological, metals, pesticides, and solvents samples will be drawn from container #1.

Table 1 – Process Lot Sampling (4.58 kg+): One Container Method

Sample #	Chemistry & Micro
1	2.10
2	1.40
3	1.40
4	1.40
5	1.40
6	1.40
7	1.40
8	1.40
9	1.40
10	1.40
11	1.40
12	1.40
13	1.40
14	1.40
15	1.40
Total Min. Mass	**24.50**

3.0 Process Lot Sampling

3.2 – Standard Sampling - Process Lots

For sampling at the process lot stage, extracts should be thoroughly mixed before sampling to ensure homogenization of the sample. Samples of medical cannabidiol process lots should be collected following final refinement, but before being used to formulate products. Standard sampling of process lots shall be in accordance with **Table 1**:

Table 2 – Standard Process Lot Sampling		
Process Lot Weight		**Sample Increments Required (1.40g ± 0.2g)**
Pounds	**Kilograms**	**# of Samples**
0-0.50	0-0.23	2
0.50-1.50	0.24-0.68	4
1.51-3.00	0.69-1.36	6
3.10-6.0	1.40-2.72	8
6.10-10.00	2.77-4.54	10
10+	4.58+	15

For both standard and reduced-testing process lots, a laboratory shall provide the necessary weighed and designated containers to a manufacturer. For example, for a 4.58+ Kilogram process lot, sampling will follow the method as outlined in **Table 1.** Mass is sampled in grams for all analytes. The number indicates the mass of process lot necessary per sample.

Example: If a manufacturer completes a 4.58+kg process lot, they shall withdraw 15 independent samples in accordance with **Table 2**, using the one container method described in **Table 1**. Once delivered, each sample will have three tests performed, for a total of 45 tests.

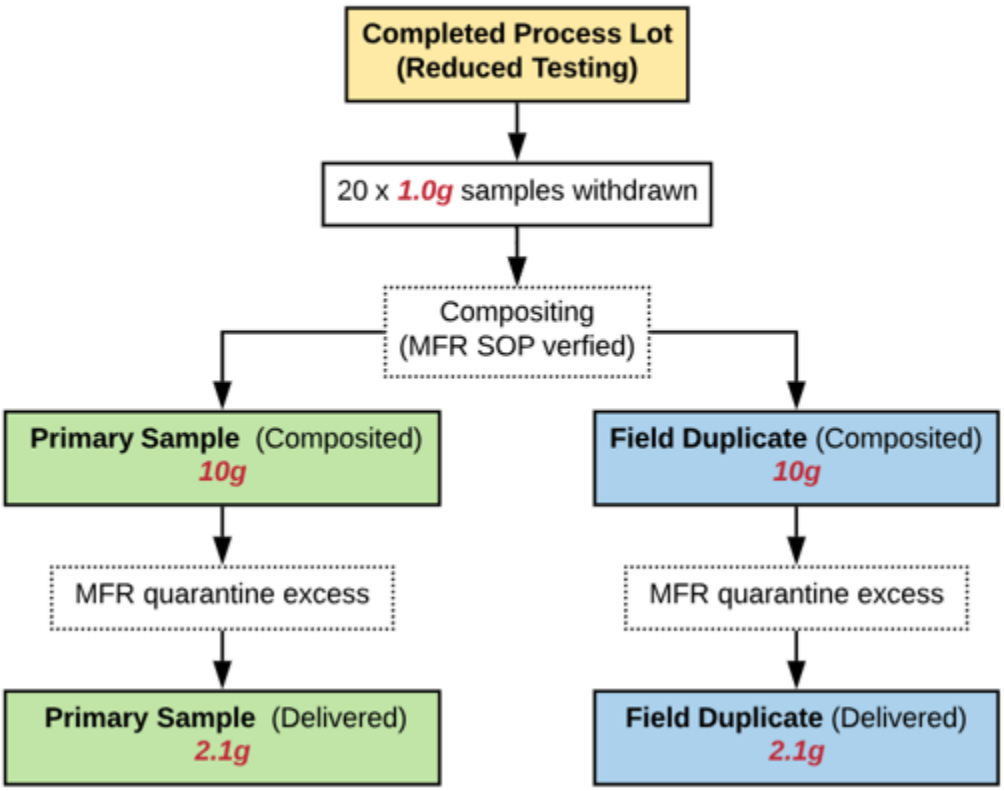
3.3 – Reduced Sampling - Process Lots

Once a manufacturer has passed standard testing for a method of extraction and purification for process lots, the manufacturer shall enter into reduced-testing status for the extraction and purification process. Upon completion of a process lot by a manufacturer in reduced-testing status, a manufacturer shall withdraw 20, 1.0g samples from the process lot. These 20 samples shall be composited by a manufacturer into a *10.0g primary sample, and a 10.0g field duplicate*. The SOP for compositing samples in reduced testing shall be submitted to the Department, and physically verified and approved by the Department or a laboratory.

3.0Process Lot Sampling

Quarantining of excess process lot material in reduced testing: Once a manufacturer's sampling SOP is verified, a manufacturer may withdraw the required amount of process lot from the primary sample and field duplicate that is required for a laboratory to complete the required testing. The remainder of the primary sample and field duplicate shall be quarantined by a manufacturer (see **Table 3**). If it is determined that a laboratory requires more material to complete the testing, a manufacturer shall deliver material from the process lot that was quarantined by the manufacturer. If the process lot(s) pass all testing, the remainder of the process lot being quarantined by the manufacturer may be reintroduced to the original lot from which it was drawn.

Table 3 – Reduced Process Lot Sampling



4.0 Process Lot Testing

4.1 – Process Lot Testing Overview

Testing of process lots made by a manufacturer is designed to determine the safety of process lots produced through a specific extraction process. Once standard testing is successfully completed, a manufacturer will enter reduced-testing status on subsequent process lots using the same extraction process.

Contaminants tested at the process lot level include:

- Pesticides
- Residual Solvents and Processing Chemicals
- Metals

4.2 – Process Lot Pass Criteria

A laboratory will use the following criteria to determine whether a process lot passes testing for the required analytes at the process lot level:

- Solvents and processing chemicals cannot be present at or above the action levels described in **Table 5**.
- Metals cannot be present above at or above the action levels described in **Table 5**.
- Pesticides cannot be present at or above the action levels described in **Table 7**.

4.3 – Standard Testing - Process Lots

During standard testing for process lots, the laboratory will test each sample unit independently in accordance with **Table 2,** using the one container method in **Table 1**. A laboratory shall conduct one test for each required analyte on each independent sample. A laboratory shall report that a process lot passed if no test result meets or exceeds the action levels in the tables referenced in **Section 4.2**.

4.0 Process Lot Testing

4.4 – Reduced Testing - Process Lots

Once a manufacturer successfully completes a single round of standard testing, a manufacturer will enter into reduced-testing status on subsequent process lots using the same extraction process. A manufacturer may remain in reduced-testing status for two years for an approved extraction process, unless material changes are made to the extraction process (see **Section 4.5**). A laboratory shall report that a process lot passed if no test result meets or exceeds the action levels in **Section 4.2**.

Sampling for reduced testing process lots shall be in accordance with **Table 3**. A laboratory shall conduct testing for process lot analytes on both the primary and field duplicate sample, for a total of eight tests.

4.5 – Alterations to Processes or Standard Operating Procedures for Process Lots

Material changes to a manufacturing process may require a manufacturer to return to standard testing for that extraction and purification process. Changes to a manufacturing process that may require a return to standard testing include, but are not limited to, changes in the size of the production volume that would necessitate a change in machinery or process, or changes in machinery, equipment, or solvents. Manufacturers should discuss any change in process with the Department to determine whether this would require a return to standard testing for a given extraction process.

5.0 Packaged Lot Sampling

5.1 – Packaged Lot Sampling Plan Overview

For sampling at the packaged lot stage, manufacturers shall submit samples of packaged products prior to delivering or transferring the products to dispensaries. Samples sent for testing should include all excipients and other ingredients that are in final products, and shall be representative of final packaged products. Manufacturers must contact the laboratory in advance to schedule a transfer of samples.

5.2 – Standard Packaged Lot Sampling

Standard packaged lot sampling shall be random, and follow the strategy as outlined in **Table 4**.

Table 4 – Standard Packaged Lot Sampling

Units Produced	Sample Units	Reserve Samples (*retained by the manufacturer*)
2-15	2	1
16-50	3	1
51-150	5	1
151-500	8	1
501-3,200	13	1
3,201-35,000	20	1

For each packaged lot, a manufacturer shall retain a uniquely labeled reserve sample, consisting of twice as much as is necessary to perform all the required tests. The sample shall represent each packaged lot of medical cannabidiol, and shall be stored for two years under conditions consistent with product labeling and in the same or similar container-closure system in which the product is marketed and sold (641 IAC 154.26(5)).

5.3 – Reduced Packaged Lot Sampling

Once a manufacturer's process has passed standard testing for packaged lots and enters into reduced-testing status, a manufacturer shall randomly withdraw two finished containers of a given formulation or SKU from a completed packaged lot. The SOP for withdrawing random samples in reduced-testing status shall be submitted to the Department, and physically verified and approved by the Department or a laboratory.

6.0 Packaged Lot Testing

6.1 – Packaged Lot Testing Overview

Testing of packaged lots made by a manufacturer is designed to determine the potency and microbiological purity of the lot. Once a manufacturer's formulation and packaging process successfully passes a single round of standard testing, a manufacturer will enter into reduced-testing status on subsequent packaged lots using the same formulation and packaging process. Sampling will be done by formulation or SKU. Results for both microbiological impurities and potency will be attached to the unique identifier for the specific formulation of a packaged lot that a manufacturer delivers to the laboratory.

Testing of a packaged lot will include:

- Potency – THC, THCa, CBD, CBDa (testing for THCa and CBDa will not be included if a manufacturer uses a decarboxylation process prior to extraction)
    - A laboratory will test samples against a concentration claim for THC and CBD that is submitted by the manufacturer. A manufacturer must provide the laboratory with a label claim for THC and CBD for each formulation.
- Microbiological impurities (tests are based on product matrix, see **Table 6)**.

6.2 – Packaged Lot Pass Criteria

A laboratory will use the following criteria to determine whether a packaged lot passes testing:

- All samples test ± 30% of the labeled concentrations for THC and CBD, in mg/g for solids and mg/ml for liquids.
- The concentration of THC in any sample does not exceed 3% (with adjustment for uncertainty associated with the laboratory method).
- The Relative Standard Deviation (RSD) of the mean concentration of THC and CBD in the samples is equal to or less than 20% for *standard testing.*
- The Relative Percent Difference (RPD) of the mean concentration of THC and CBD in the samples is equal to or less than 20% for *reduced testing*.
- Microbiological impurities do not meet or exceed action levels as described in **Table 6.**

6.0 Packaged Lot Testing

6.3 – Standard Testing - Packaged Lots

During standard testing for packaged lots, a manufacturer will randomly sample units based on **Table 4**. Sampling will be done by formulation or SKU. Results for both microbiological impurities and potency will be attached to the unique identifier for the specific formulation or SKU of packaged lot that a manufacturer delivers to the laboratory.

From the packaged lot samples of a given formulation that arrive at the laboratory, a laboratory shall choose three individual containers to perform three microbiological impurity suites, which varies by matrix according to **Table 6**. In addition, a laboratory will conduct 30 potency tests per formulation or SKU. The laboratory shall determine the RSD of these 30 samples, which shall not be greater than 20%. This means there will be 36-42 tests per formulation or SKU for standard testing of packaged lots.

Example: If a manufacturer has 700 units of 1:1 CBD:THC capsules in standard testing, the manufacturer shall submit 13 containers of the formulation to the laboratory for testing. A laboratory shall choose 3 containers, and shall conduct a microbiological impurity suite on a sample from each container. In addition, the laboratory will randomly draw 30 capsules from these 13 units to conduct the 30 potency tests, and the laboratory shall report the RSD of these 30 potency tests.

6.4 – Reduced Testing - Packaged Lots

Once a manufacturer successfully completes standard testing for a formulation and packaging process for a packaged lot, a manufacturer will enter into reduced-testing status on subsequent packaged lots using the same formulation and packaging process. A manufacturer may remain in reduced-testing status for two years for an approved formulation and packaging process, unless material changes are made to the process (see **Section 6.6**). A laboratory shall report that a packaged lot passed if all criteria in **Section 6.2** are met.

Sampling for reduced-testing status of packaged lots shall include one primary sample and one field duplicate in the form of two containers from each formulation or SKU of packaged lot. A laboratory shall conduct one microbiological impurities suite on the primary sample. For potency, a laboratory shall test a sample from both the primary sample and field duplicate, and run the RPD of the two samples. The RPD shall not be greater than 20%. This means there will be a total of 4-6 tests per formulation or SKU for reduced testing of packaged lots.

6.0 Packaged Lot Testing

Example: If a manufacturer makes 700 units of 1:1 CBD:THC capsules in reduced testing, they shall submit two, randomly sampled units of the formulation or SKU to the laboratory for testing. A laboratory shall conduct a microbiological impurity suite on the primary sample. Additionally, the laboratory will randomly select a capsule from both the primary sample and field duplicate and conduct a potency test on each, and report the RPD of the two tests.

6.5 – Vaporizer Cartridge Validation for Lead Contamination

The following refers to both vaporizer cartridges and disposable vaporizer units. It is recommended that manufacturers perform due diligence on the manufacturer or vendor of the vaporizer cartridges prior to purchasing, and consider requesting available certificates of analysis. When a manufacturer orders a new lot of empty cartridges, the first lot of cartridges that are filled and delivered to the laboratory for packaged lot testing shall also undergo three tests for lead, regardless of production volume. The action level for these tests shall be 1.0 ppm. All of three test results must be less than the action level to achieve a pass.

Once an order of cartridges passes these three tests, a manufacturer will not have to retest cartridges for lead until it orders a new lot of empty cartridges. Upon report of a failure, that lot of cartridges shall have a single opportunity for a retest. This retest shall include the delivery of enough cartridges from the same lot to perform three tests. If any of the three tests fail, that lot of cartridges shall be destroyed.

Any new order of cartridges ordered by a manufacturer must undergo three tests for lead contamination. A manufacturer shall notify the Department and laboratory when they order a new lot of cartridges. Manufacturers should be aware that additional, filled cartridges may be necessary for a laboratory to accomplish these three tests.

6.6 – Alterations to Processes or Standard Operating Procedures for Packaged Lots

Material changes to a manufacturing formulation and packaging process may require a manufacturer to return to standard testing for that formulation and/or process. Changes to a manufacturing process that may require a return to standard testing include, but are not limited to changes in the ratio of CBD to THC; changes in the size of the production volume that would necessitate a change in machinery, processes, or equipment; or changes in the level of automation (e.g., switch from manual to an automated processes). Manufacturers should discuss any change in process with the Department to determine whether this would require a return to standard testing for a given formulation. In relation to the above, the basic criteria used to consider a return to standard testing are: potential impacts to homogeneity, contamination, and label claim.

7.0 Failure Process – Process and Packaged Lots

7.1 – Process lot Failure – Standard & Reduced Testing

If a failure occurs for any of the listed contaminants at the process lot stage, pursuant to 641 IAC 156.26(3)"*c"*, the manufacturer shall refrain from further formulating any medical cannabidiol products with the failed process lot. Medical cannabidiol from a process lot that fails contaminant testing at the process lot stage may be remediated and resampled in accordance with standard testing procedures (see **Table 2***). During a retest, a laboratory shall only conduct the test for the analyte that failed the initial testing.* A manufacturer will retain this remediation option at the process lot stage in perpetuity, assuming remediation is possible. Upon passing under standard testing procedures for the analyte in question, a laboratory shall report the first test(s) as having failed, and the second test(s) to have passed. A subsequent process lot using the same extraction and purification will be in reduced testing status.

7.2 – Packaged lot Failure – Standard & Reduced Testing

If a failure for potency or microbiological impurities occurs during the standard testing of packaged lots, the following shall apply. For potency, if there is a failure and the lots cannot be remedied by relabeling, or any of the criteria in **Section 6.2** are not met, the manufacturer may have a single opportunity to retest the formulation of packaged lot as described in the sections below. *During a retest, a laboratory shall only conduct the test for the analyte that failed initial testing.* If a manufacturer chooses not to retest, or the formulation fails the criteria on the retest, the manufacturer shall reject and destroy the products, unless otherwise described in the sections below.

1. Potency Failure
    - THC > 3% + the Measurement of Uncertainty (MU)
        - If it is reported that the average THC percentage of a formulation or SKU of packaged lot is greater than 3% + MU, that lot shall not have the opportunity for a retest and shall be destroyed.
    - 30% criterion (Relabeling)
        - Re-labeling in standard testing may occur if samples consistency fail the ±30% such that they could qualify for an alternative label claim. If any standard testing samples fail the ±30% criterion, it will be determined whether the failure can be remedied by relabeling the packaged lot such that all samples test within ±30% of the new labeled concentrations. If so, the laboratory will fail the formulation for the original label, but will then pass the formulation for the new label concentration. Such relabeling will still allow the formulation to pass or remain in reduced testing for the new label claim.

7.0 Failure Process – Process and Packaged Lots

- If samples in standard testing fail the ±30% criterion and cannot be remedied by relabeling, the formulation of packaged lot will have a single opportunity for a retest. Thirty (30) additional, new samples will be taken from the packaged lot formulation that the lab has on hand. If the lab does not have enough samples to achieve 30 tests, the manufacturer shall deliver enough samples of the identical package lot in order to achieve these 30 tests. If, upon a retest, the results are within ±30% of a label claim, a laboratory shall report the first test as having failed, and the second as having passed. Upon a reported pass, the formulation shall enter or remain in reduced testing. If upon a retest, there are samples not within ±30% of label claim, the Department reserves the right to determine whether a manufacturer must reject and destroy that package lot, as well as if that packaged lot formulation will remain in reduced testing status."

- RSD (standard testing) or RPD (reduced testing) >20%
  - If in standard testing the RSD of a formulation or SKU of packaged lot exceeds 20%, or if in reduced testing the RPD exceeds 20%, a laboratory shall conduct 30 new potency tests from the same lot of a given product matrix (capsules, tincture, etc.). If the laboratory does not have enough existing material on-hand to conduct the necessary tests, the manufacturer shall deliver enough new containers of the identical lot to complete the necessary tests. In the event of this failure, a manufacturer shall discuss with a laboratory how much material will be needed to conduct these tests. If, upon a retest, the results are < 20% RSD in standard testing and < 20% RPD in reduced testing, a laboratory shall report the first test as having failed, and the second as having passed.

2. Microbiological Impurities Failure
   - Total Yeast & Mold Count (TYMC) and Total Aerobic Microbial Count (TAMC)
     - If any packaged lot fails TYMC or TAMC for the action levels described in **Table 6**, a manufacturer will have a single opportunity for a retest.
     - A manufacturer shall deliver two new containers (primary sample and field duplicate) of the formulation(s) in question, drawn from the same lot as the original samples. A laboratory will conduct three new tests for TYMC on the new primary sample and field duplicate. No one test can be greater than the action levels described in **Table 6**. If any one test exceeds the action levels for microbiological impurities, the packaged lot of that formulation must be destroyed. If all three tests pass, a laboratory shall report the first test as having failed, and the second to have passed. Upon a reported pass, the formulation shall enter or remain in reduced-testing status.
   - Aspergillus, Shiga Toxin producing *E. coli* (STEC) and Salmonella

- If at any point a formulation or SKU of a packaged lot fails any of the pathogen tests within the microbiological impurities suite, that packaged lot shall not have an opportunity for a retest and shall be destroyed.

8.0 Contaminant Analyses and Acceptance Criteria

Approved laboratories and licensed manufacturers should refer to **Table 5** for guidelines for product testing and acceptance criteria.

Table 5 - Contaminant Analysis & Acceptance Criteria			
Analyte	Action Level	Comment	Guideline
Metals		Metals testing is required for every process lot, also for initial vaporizer cartridge validation (**see Section 6.5**)	FDA Q3D, elemental impurities guidance
Arsenic	1.5 ppm		
Cadmium	0.3 ppm		
Lead	1.0 ppm		
Mercury	0.5 ppm		
Analyte	Action Level	Comment	Guideline
Microbiological Impurities	See **Table 6**	Microbial tests (Total combined yeast and molds) are required for all packaged lots	American Herbal Pharmacopeia (USP 1111), State of Iowa Hygienic Laboratory
Analyte	Action Level	Comment	Guideline
Pesticides	See **Table 7**	Pesticide Testing is required for every process lot	APHL "Guidance for State Medical Cannabis Testing Programs" (2016)
Analyte	Action Level	Comment	Guideline
Solvents		Solvent testing is required for every process lot	Based on disclosed use by manufacturer
Ethanol	5000 ppm		

**For all contaminants, a test shall be reported as having failed if the analyte concentration is greater than or equal to the action level approved by the department and listed in this document.*

8.0 Contaminant Analyses and Acceptance Criteria

Table 6 – Microbiological Impurities & Acceptance Criteria				
Microbiological Test	**Testing Stage (Lot)**	**Consumable products**	**Inhalable products**	**Non-consumable Products (Topical, Suppositories)**
Total aerobic microbial count	Packaged	$1x10^3$ CFU/g Max acceptable count: 2000	$1x10^2$ CFU/g Max acceptable count: 200	$1x10^3$ CFU/g Max acceptable count: 2000
Total combined yeasts molds count	Packaged	$1x10^2$ CFU/g Max acceptable count: 200	$1x10^1$ CFU/g Max acceptable count: 20	$1x10^2$ CFU/g Max acceptable count: 200
Aspergillus (*A.fumigatus, A. flavus, A. niger, A. terreus)**	Packaged		$1x10^2$ CFU/g Max acceptable count: 200	
Shiga-Toxin Producing *E.coli*	Packaged	No detection in 1 g	No detection in 1 g	
Salmonella	Packaged	No detection in 1 g	No detection in 1 g	

**Results for this test will only be reported when mold is found on the Total Combined Yeasts Molds Count.*

8.0 Contaminant Analyses and Acceptance Criteria

Table 7 – Pesticide Analytes and Action Levels		
Analyte	**Chemical Abstract Services (CAS) Registry Number**	**Action Level (ppm)**
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.5
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorpyrifos	2921-88-2	0.6
Cypermethrin	52315-07-8	18
Diazinon	333-41-5	2.6
Dichlorvos	62-73-7	0.1
Ethoprophos	13194-48-4	0.4
Etofenprox	80844-07-1	0.4
Fipronil	120068-37-3	1
Flonicamid	158062-67-0	1
Imidacloprid	138261-41-3	0.4
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.4
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	8.5
Myclobutanil	88671-89-0	0.3
Oxamyl	23135-22-0	1
Permethrin I	52465-53-1	1.1
Pyridaben	96489-71-3	0.2
Spiroxamine I	118134-30-8	2
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2

9.0 – Stability Testing

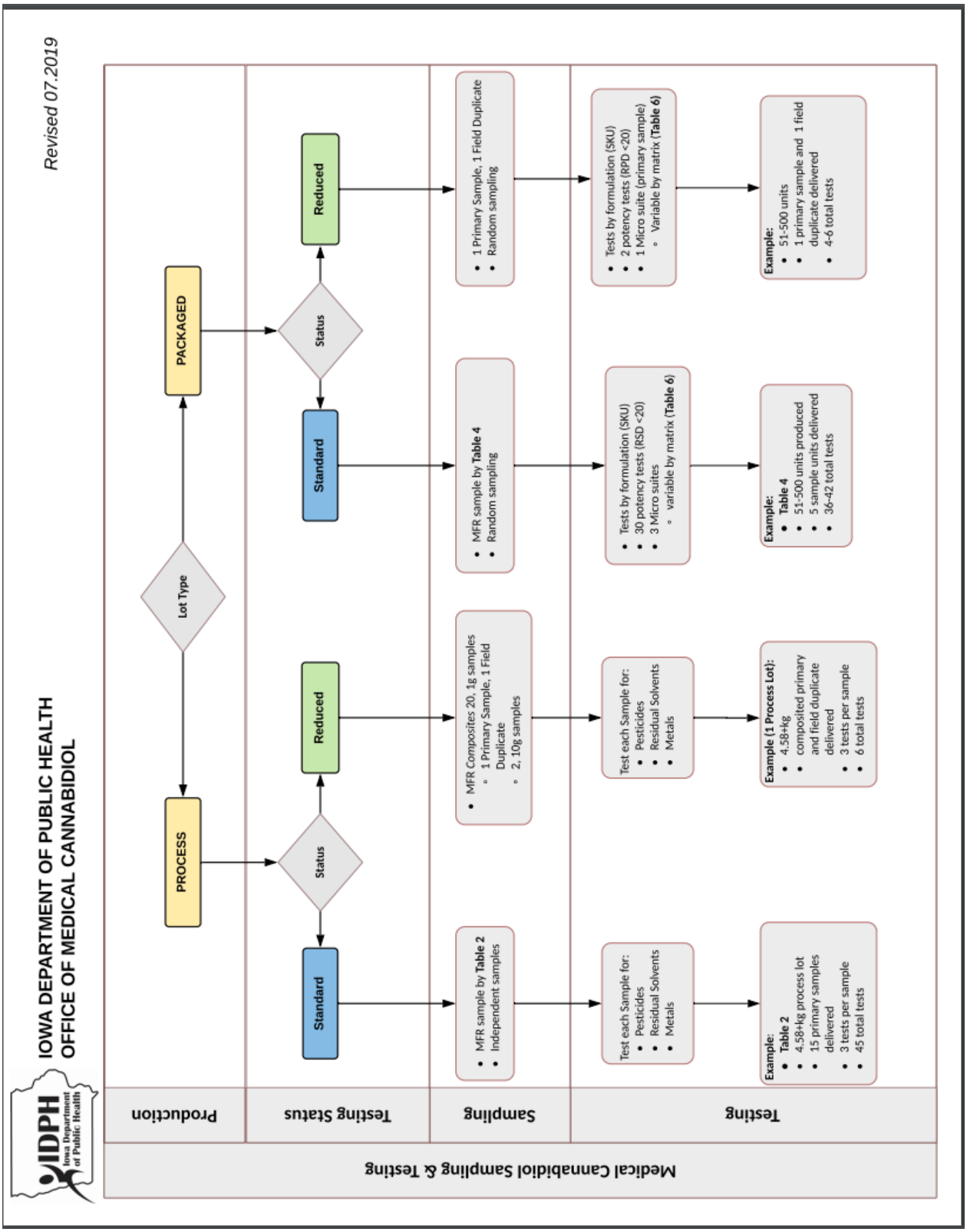
As a part of a quality control program, manufacturers shall develop procedures for performing stability testing of each product type that is manufactured. Stability testing shall be done in the same container-closure system in which the product is sold. Stability testing shall be conducted by the manufacturer. Licensed manufacturers should refer to **Table 8** guidelines for sample size and testing intervals for stability testing.

Table 8 – Stability Testing

Product	Sample size tested at each interval	Sample container	Storage Conditions	Intervals (months)					
Capsule	3 capsules	White Plastic Bottle	Room Temp.	0	3	6	9	12	18
Suppository	3 suppositories	Blister Pack	Room Temp.	0	3	6	9	12	18
Tincture	0.5 mL	Amber Glass Bottle	Room Temp.	0	3	6	9	12	18
Lotion	1.0 mL	White Plastic Bottle	Room Temp.	0	3	6	9	12	18
Vaporization	3 cartridges, or disposable units	Cartridge, or disposable units	Room Temp.	0	3	6	9	12	18

If product-expiration-date studies have not been completed before a manufacturer begins delivering products to dispensaries, the manufacturer shall assign a tentative product expiration date, not to exceed one year, based on any available stability information (641 IAC 154.26(4)).

Appendix A – Sampling and Testing Flow Char



Appendix B – Testing Failure Process